

## RULEMAKING NOTICE FORM

Notice Number	<b>2015-132</b>	Rule Number	<b>He-P4032, He-P 4033 &amp; He-P 4034</b>
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1. Agency Name & Address:  <b>NH Department of Health and Human Services          Division of Public Health Services          Radiological Health Section (RHS)          29 Hazen Drive          Concord, NH 03301</b>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;">           2. RSA Authority:             3. Federal Authority:             4. Type of Action:                Adoption                Amendment                Repeal                Readoption                Readoption w/amendment         </td> <td style="width: 50%; vertical-align: top; border-left: 1px solid black; padding-left: 10px;"> <div style="text-align: center;"><b>RSA 125-F:5, V, F:7, I &amp; III</b></div> <hr/> <div style="text-align: center;"><b>10 CFR Parts 32, 33 &amp; 34</b></div> <hr/> <div style="text-align: center;"> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto;"></div> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto;"></div> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto;"></div> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto;"></div> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto; text-align: center;"><b>X</b></div> </div> </td> </tr> </table>	2. RSA Authority:  3. Federal Authority:  4. Type of Action: Adoption Amendment Repeal Readoption Readoption w/amendment	<div style="text-align: center;"><b>RSA 125-F:5, V, F:7, I &amp; III</b></div> <hr/> <div style="text-align: center;"><b>10 CFR Parts 32, 33 &amp; 34</b></div> <hr/> <div style="text-align: center;"> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto;"></div> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto;"></div> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto;"></div> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto;"></div> <div style="border-bottom: 1px solid black; width: 100px; margin: 0 auto; text-align: center;"><b>X</b></div> </div>
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5. Short Title: **Specific Licenses for Manufacture or Transfer of Certain Items Containing Byproduct Material, Specific Licenses of Broad Scope for Other Than Human Use, and Radiation Safety Requirements for Industrial Radiographic Operations**

6. (a) Summary of what the rule says and of any proposed amendments:

**The current rules are scheduled to expire on August 7, 2015, but are subject to extension under RSA 541-A:14-a. The rules are being updated so that the terms and requirements maintain consistency with amendments to federal regulations. The proposed rules readopt with amendment He-P 4032, 4033 and 4034. The amended rules replace “radioactive material” with the term “byproduct material.” The Atomic Energy Act, as revised in 1978 and 2005 by the Energy Policy Act (EP Act), defines byproduct material as radioactive material, excepting special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or using special nuclear material.**

**He-P 4032 states requirements for manufacturers or initial transferors of a sealed source or devices containing a sealed source used by either persons specifically licensed under He-P 4030, “Licensing of Radioactive Material,” or persons who are licensed by the equivalent regulations of an agreement state, which is operating under an agreement with the Nuclear Regulatory Commission (NRC), or a licensing state.**

**He-P 4032.13-He-P 4032.16 are proposed new sections describing requirements for certain licensees now generally regulated under He-P 4000. He-P 4032.13 requires serial numbers for tracking byproduct materials of certain sources, which, when manufactured, have the potential to trigger national security concerns. He-P 4032.14 requires a specific license to manufacture, or initially transfer, calibration reference sources containing Americium-241 or Radium-226 for distribution to persons generally licensed. He-P 4032.15 states requirements for the manufacture and distribution of byproduct material for certain in-vitro clinical or laboratory testing under a general license, and describes packaging for acceptable units and safety labeling requirements. He-P 4032.16 describes requirements for the approval of an application for a specific license to manufacture, or initially transfer ice detection devices containing strontium 90.**

**He-P 4033 states requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing those licensees. The proposed rule replaces the term “radioactive material” with the term “byproduct material.”**

**He-P 4034 states the requirements for the issuance of licenses and registrations for the industrial use of sources of radiation, and radiation safety requirements for persons using sources of radiation in industrial radiography. The rule now incorporates by reference the American National Standard Institute “Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography,” and adds an alternative wearing device, an optically stimulated luminescence dosimeter, for use by radiographers and assistant radiographers. The proposed rule clarifies some existing definitions.**

6. (b) Brief description of the groups affected:

**The proposed rules affect businesses related to industrial radiography, and other businesses, hospital diagnostic and treatment centers, and research groups that use byproduct material.**

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

<b>Rule</b>	<b>State Statute or Federal Regulation</b>
He-P 4032	Section 274 of the AEA of 1954, as amended, and Title 10 CFR Part 32
He-P 4032.01	10 CFR 32.1
He-P 4032.02	10 CFR 32.1(b)
He-P 4032.03	10 CFR 32.51
He-P 4032.04	10 CFR 32.11
He-P 4032.05	10 CFR 32.72
He-P 4032.06	10 CFR 32.72
He-P 4032.07	10 CFR 32.74
He-P 4032.08	10 CFR 32.53
He-P 4032.09	10 CFR 32.18
He-P 4032.10	10 CFR 32.26
He-P 4032.11	10 CFR 32.14
He-P 4032.12	10 CFR 32.13
He-P 4032.13	10 CFR 32.201
He-P 4032.14	10 CFR 32.57
He-P 4032.15	10 CFR 32.51
He-P 4032.16	10 CFR 32.61, 10 CFR 32.62
He-P 4033	Section 274 of the AEA of 1954, as amended, and Title 10 CFR Part 33
He-P 4033.01	10 CFR 33.1
He-P 4033.02	10 CFR 33.1
He-P 4033.03	10 CFR 33.11
He-P 4033.04	10 CFR 33.12
He-P 4033.05	10 CFR 33.13, 33.14, 33.15
He-P 4033.06	10 CFR 33.17
He-P 4033.07	10 CFR 33.100, Schedule A
He-P 4034	Section 274 of the AEA of 1954, as amended, and Title 10 CFR Part 34; Title 21 CFR Part 1020
He-P 4034.01	10 CFR 34.1
He-P 4034.02	10 CFR 34.1
He-P 4034.03	10 CFR 34.3, 21 CFR 1020.40
He-P 4034.04	10 CFR Part 34, Subpart G (10 CFR 34.111); 21 CFR 1020.40
He-P 4034.05	10 CFR Part 34.11, 34.13
He-P 4034.06	10 CFR 34.20
He-P 4034.07	10 CFR 34.21
He-P 4034.08	10 CFR 34.23

<b>Rule</b>	<b>State Statute or Federal Regulation</b>
He-P 4034.09	10 CFR 34.25
He-P 4034.10	10 CFR 34.27
He-P 4034.11	10 CFR 34.29
He-P 4034.12	10 CFR 34.31
He-P 4034.13	10 CFR 34.33
He-P 4034.14	10 CFR 34.35
He-P 4034.15	10 CFR 34.41
He-P 4034.16	10 CFR 34.42
He-P 4034.17	10 CFR 34.43
He-P 4034.18	10 CFR 34.45
He-P 4034.19	10 CFR 34.46
He-P 4034.20	10 CFR 34.47
He-P 4034.21	10 CFR 34.49
He-P 4034.22	10 CFR 34.51
He-P 4034.23	10 CFR 34.53
He-P 4034.24	10 CFR 34.61
He-P 4034.25	10 CFR 34.63
He-P 4034.26	10 CFR 34.65
He-P 4034.27	10 CFR 34.67
He-P 4034.28	10 CFR 34.69
He-P 4034.29	10 CFR 34.71
He-P 4034.30	10 CFR 34.73
He-P 4034.31	10 CFR Part 34, Subpart E (10 CFR 34.75)
He-P 4034.32	10 CFR 34.79
He-P 4034.33	10 CFR 34.81
He-P 4034.34	10 CFR 34.83
He-P 4034.35	10 CFR 34.85
He-P 4034.36	10 CFR 34.87
He-P 4034.37	10 CFR 34.89
He-P 4034.38	10 CFR 34.101
He-P 4034.39	10 CFR 34.41
He-P 4034 Appendix A	10 CFR Part 34, Appendix A

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: **Catherine Bernhard** Title: **Rules Coordinator**  
Address: **Dept. of Health and Human Services** Phone #: **271-9374**  
**Administrative Rules Unit** Fax#: **271-5590**  
**129 Pleasant St.** E-mail: [catherine.bernhard@dhhs.state.nh.us](mailto:catherine.bernhard@dhhs.state.nh.us)  
**Concord, NH 03301**

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

**The proposed rules may be viewed and downloaded at:**

<http://www.dhhs.nh.gov/oos/aru/comment.htm>

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **Thursday September 3, 2015**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Thursday, August 27, 2015 at 1:00 PM**

Place: **DHHS Brown Bldg., Room 288, 129 Pleasant St., Concord, NH**

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # **15:135**, dated **07/27/15**

**1. Comparison of the costs of the proposed rule(s) to the existing rule(s):**

There is no difference in cost when comparing the proposed rules to the existing rules.

**2. Cite the Federal mandate. Identify the impact of state funds:**

The Atomic Energy Act as revised in 1978 and 2005 by the Energy Policy Act. There will be no impact on State funds.

**3. Cost and benefits of the proposed rule(s):**

**A. To State general or State special funds:**

None.

**B. To State citizens and political subdivisions:**

None.

**C. To Independently owned businesses:**

None.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

**The proposed rule modifies an existing program or responsibility, but does not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore does not violate Part I, Article 28-a of the N.H. Constitution.**

**Readopt with amendment He-P 4032, effective 8-7-07 (Document # 8959), to read as follows:**

PART He-P 4032 SPECIFIC LICENSES FOR MANUFACTURE OR TRANSFER OF CERTAIN ITEMS CONTAINING RADIOACTIVE BYPRODUCT MATERIAL

He-P 4032.01 Purpose.

(a) This part shall prescribe requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing radioactive byproduct material for sale or distribution to:

- (1) Persons exempted from the licensing requirements of He-P 4030; and/or
- (2) Persons generally licensed under He-P 4031 or He-P 4035.

(b) This part shall prescribe requirements for manufacturers or initial transferors of sealed source or devices containing sealed sources which are to be used by persons specifically licensed under He-P 4030 and U.S. Nuclear Regulatory Commission (NRC) in 10 CFR Part 37 or equivalent regulations of the NRC, an Agreement State or a Licensing State.

He-P 4032.02 Scope. The provisions and requirements of this part shall be in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of He-P 4030 apply to applications, licenses and certificates of registration subject to He-P 4032, and the provisions of U.S. Nuclear Regulatory Commission in 10 CFR Part 37 apply to applications and licenses subject to He-P 4032.

He-P 4032.03 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed.

(a) An application for a specific license to manufacture or initially transfer devices containing ~~radioactive material~~ byproduct material, excluding special nuclear material, to persons generally licensed under He-P 4031.04, or equivalent regulations of the NRC, or an Agreement State as established by the Atomic Energy Act of 1954, or a Licensing State shall be approved if:

- (1) The applicant satisfies the general requirements of He-P 4030.09;

(2) The applicant submits complete information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device which shall assure to provide assurance that:

- a. The device can be safely operated by persons not having training in radiological protection;
- b. Under ordinary conditions of handling, storage, and the use of the device, the ~~radioactive material~~ byproduct material contained in the device cannot be released or inadvertently removed from the device;

c. Under ordinary conditions of handling, storage, and the use of the device, it is unlikely that any person will receive in one year a dose in excess of 10% of the annual limits specified in He-P 4020.05; and

d. Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the organ doses in Table 4032.1 below:

Table 4032.1 Organ Doses Under Accident Conditions

Body Part	Organ Dose
<u>Whole body; head and trunk; active blood-forming organs; gonads, or lens of eye</u>	15 rems (150 mSv)
Hands and forearms; feet and localized areas of skin averaged over areas no longer than 1 square centimeter	200 rems (2 Sv)
Other organs	50 rems (500 mSv);

(3) Each device bears a durable, legible, clearly visible label or labels, which contain in a clearly identified and separate statement:

a. Instructions and precautions necessary to assure safe installation, operation, and servicing of the device or identification of operating and service manuals used to provide this information;

b. The requirement, or exemption of a requirement, for leak testing, or for testing any on-off mechanism and indicator, to include the maximum time interval for such testing, the identification of radioactive material by isotope, the quantity of radioactivity, and the date of determination of the quantity; and

c. The information called for in the following statement in the same form:

1. "The receipt, possession, use and transfer of this device Model\_\_\_\_\_ Serial No.\_\_\_\_\_ are subject to a general license or the equivalent and the regulations of the NRC, the Agreement State or the Licensing State which has regulatory authority.";

2. "This label shall be maintained on the device in a legible condition.";

3. "Removal of this label is prohibited.";

4. The words, "CAUTION - RADIOACTIVE MATERIAL"; and

5. The name of the manufacturer or distributor;

(4) Each device having a separable source housing that provides the primary shielding for the source also bears on the source housing, a durable label containing:

- a. The device model number and serial number;
- b. The isotope and quantity;
- c. The words, "CAUTION - RADIOACTIVE MATERIAL";
- d. The radiation symbol described in He-P 4022.11; and
- e. The name of the manufacturer or initial distributor; ~~and~~

(5) Each device meeting the criteria of He-P 4031.04(e)(15), bears a permanent, such as embossed, etched, stamped, or engraved, label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "CAUTION-RADIOACTIVE MATERIAL", and, if practicable, the radiation symbol described in He-P 4022.11-; ~~and~~

(6) The device has been registered in the [NRC Sealed Source and Device Registry](#).

(b) Should an applicant under He-P 4032.03(a)(3)b. desire that a device be required to be leak tested or tested for proper operation of the on-off mechanism and indicator, at intervals greater than 6 months, ~~the~~ DHHS/[BRH-RHS](#) shall consider at least the following information in determining the acceptable interval:

- (1) Primary containment (source capsule);
- (2) Protection of primary containment;
- (3) Method of sealing containment;
- (4) Containment construction materials;
- (5) Form of contained radioactive material;
- (6) Maximum temperature withstood during prototype test;
- (7) Maximum pressure withstood during prototype tests;
- (8) Maximum quantity of contained radioactive material;
- (9) Radiotoxicity of contained radioactive material; and
- (10) Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant under He-P 4032.03(a) desires that the general licensee under He-P 4031, or under equivalent regulations of the NRC, an ~~A~~greement ~~S~~tate, or a ~~L~~icensing ~~S~~tate, be authorized to install the device, collect the sample to be analyzed by a

specific licensee for leakage of ~~radioactive material~~ byproduct material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall:

- (1) Include written instructions to be followed by the general licensee;
- (2) Include the estimated calendar~~-~~quarter doses associated with such activity or activities, and bases for such estimates; and
- (3) Demonstrate that performance of such activity or activities by an individual untrained in radiological protection is unlikely to cause that individual to receive a calendar~~-~~quarter dose in excess of 10% of the limits specified in He-P 4020.

(d) If a device containing radioactive-byproduct material is to be transferred for use under the general license contained in He-P 4031.04(b), each person that is licensed under He-P 4032.03 shall provide to each person to whom a device is to be transferred, prior to transferring the device, the following:

- (1) A copy of the general license contained in He-P 4031.04(b), except if paragraphs He-P 4031.04(e)(2) through (e)(4) or He-P 4031.04(e)(~~4~~15) do not apply to the particular device, those paragraphs may be omitted;
- (2) A copy of He-P 4031.02, He-P 4030.10(jn), He-P 4021.12, He-P 4021.13, and He-P 4021.19;
- (3) A list of the services that can only be performed by a specific licensee;
- (4) Information on acceptable disposal options including estimated costs of disposal; and
- (5) An indication that ~~the~~ DHHS/~~BRH~~ RHS shall take enforcement action for improper disposal.

(e) If the transfer specified in He-P 4032.03(d)~~-~~is through an intermediate person, the information to be provided as described in He-P 4032.03(d)~~-~~shall also be provided to the intended user prior to initial transfer to the intermediate person.

(f) If radioactive-byproduct material is to be transferred in a device for use under ~~the~~ an equivalent general license of an Agreement Sstate or equivalent regulations of the NRC, or a licensing state each person that is licensed under He-P 4032.03 shall provide to each person to whom a device is to be transferred, prior to transferring the device, the following:

- (1) A copy of the Agreement Sstate's regulations equivalent to He-P 4031.02, He-P 4030.10(jn), He-P 4021.12, He-P 4021.13, and He-P 4021.19, a copy of 10 CFR §§31.5, 31.2, 30.51, 20.2201, and 20.2202, or a copy of He-P 4031.02, He-P 4030.10(jn), He-P 4021.12, He-P 4021.13, and He-P-4021.19, except if certain paragraphs of these rules do not apply to the particular device, those paragraphs may be omitted. If a copy of the Agreement Sstate's regulations equivalent to New Hampshire rules as listed in He-P 4032.03(f)(1), is provided to a prospective general licensee in lieu of the applicable Agreement Sstate's, licensing state's or NRC regulations, the copy of the agreement state's, licensing state's or equivalent regulations of the NRC ~~it~~ shall be accompanied by a note explaining that use of the

device is regulated by the ~~A~~greement ~~S~~state, licensing state or NRC, as applicable; and if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

(2) A list of the services that can only be performed by a specific licensee;

(3) Information on acceptable disposal options including estimated costs of disposal; and

(4) The name or title, address, and phone number of the contact at the ~~A~~greement ~~S~~state or licensing state regulatory agency or NRC from which additional information may be obtained.

(g) If the transfer specified in He-P 4032.03(f) is through an intermediate person, the information to be provided as described in He-P 4032.03(f) shall also be provided to the intended user prior to initial transfer to the intermediate person.

(h) In lieu of the requirements of He-P 4032.03(d) through (g), the ~~licensee-applicant~~ may propose an alternative approach to informing customers, subject to approval by ~~the~~ DHHS/~~BRH~~RHS. In its review of such a request, ~~the~~ DHHS/~~BRH~~RHS shall assure that the proposed alternative approach to informing customers:

(1) Meets the essential objectives of He-P 4032.03(d) through (g);

(2) Provides the same information as required by He-P 4032.03(d) through (g); and

(3) Is not ~~harmful inimical~~ to public health and safety.

(i) Each device that is transferred after November 17, 2005, shall meet the labeling requirements in He-P 4032.03(a)(3) through (5).

(j) If a notification of bankruptcy has been made under He-P 4030.10(gh) or the license is to be terminated, each person licensed under He-P 4032.03 shall provide, upon request, to ~~the~~ DHHS/~~BRH~~RHS, the NRC, ~~and to~~ any appropriate ~~A~~greement ~~S~~state, or licensing state records of final disposition required under He-P 4032.03(l) and (m).

(k) Each person licensed under He-P 4032.03 to initially transfer devices to generally licensed persons shall:

(1) Report, in a clear and legible report, to ~~the~~ DHHS/~~BRH~~RHS all transfers of such devices to persons for use under the general license in He-P 4031.03 and all receipts of devices from persons licensed under He-P 4031.03 including:

a. The identity of each general licensee by name and mailing address, and address location of use. If there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;

b. The name, title, and telephone number of the individual identified by the general licensee as having knowledge of and authority to take required actions to

~~ensure~~ensure compliance with the applicable rules, and who may constitute a point of contact between ~~the~~ DHHS/~~BRH~~ RHS and the general licensee;

- c. The date of transfer;
- d. The type, model number, and serial number of device transferred;
- e. The quantity and type of ~~radioactive~~ byproduct material contained in the device;
- f. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s); and
- g. The identity of the specific licensee submitting the report, including the license number of the specific licensee;

(2) Report, in a clear and legible report, to ~~the~~ DHHS/~~BRH~~ RHS all receipts of devices from persons licensed under He-P 4031.03, including, for devices received from persons generally licensed under He-P 4031.03:

- a. The identity of the general licensee by name and address;
- b. The type, model number, and serial number of the device received;
- c. The date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; and
- ~~d. The identity of the specific licensee submitting the report, including the license number of the specific licensee;~~

(3) Report to ~~the~~ DHHS/~~BRH~~ RHS the identity of the general licensee, the device, and the changes to information on the device label, if the licensee authorized under He-P 4032.03 makes changes to a device possessed by a general licensee authorized under He-P 4031.04(b), such that the label must be changed to update required information;

(4) Report to ~~the~~ DHHS/~~BRH~~ RHS if no transfers have been made to or from persons generally licensed under He-P 4031.04(b) during the reporting period;

(5) Report to the NRC, on NRC Form 653 "Transfers of Industrial Devices Report" or in a clear and legible report containing all data required by the form, all transfers of such devices to persons for use under the NRC general license in section 31.5 of 10 CFR 31;

(6) Report to the responsible ~~A~~ agreement ~~S~~ state, ~~or~~ ~~L~~ icensing ~~S~~ state agency or the NRC agency all transfers of such devices to persons for use under a general license in the ~~A~~ agreement ~~S~~ state's ~~or~~ ~~L~~ icensing ~~S~~ state's or NRC regulations equivalent to He-P 4031;

(7) Identify in the report required by He-P 4032.03(k)(5) or (6), the following:

a. The identity of each general licensee by name and mailing address, and address location of use; if there is no mailing address for the location of use, an alternative address for the general licensee shall be submitted along with information on the actual location of use;

b. The name, title, and telephone number of the individual identified by the general licensee as having knowledge of and authority to take required actions to ~~ensue~~ensure compliance with the applicable rules, and who may constitute a point of contact between the agency and the general licensee;

c. The date of transfer;

d. The type, model, and serial number of the device transferred;

e. The quantity and type of ~~radioactive~~byproduct material contained in the device;

f. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s); and

g. The identity of the specific licensee submitting the report, including the license number of the specific licensee;

(8) Report to the NRC, on NRC Form 653 "Transfers of Industrial Devices Report" or in a clear and legible report containing all data required by the form, all receipts of such devices from persons authorized under the NRC general license in section 31.5 of 10 CFR 31;

(9) Report to the responsible ~~A~~agreement ~~S~~state, or ~~L~~icensing ~~S~~state ~~agency or the NRC-agency~~ all receipts of such devices from persons authorized under a general license in the ~~A~~agreement ~~S~~state's, or ~~L~~icensing ~~S~~state's or NRC regulations equivalent to He-P 4031.04;

(10) Include in the report for devices received from persons generally licensed under either ~~A~~agreement ~~S~~state, ~~L~~icensing ~~S~~state, or NRC regulations equivalent to He-P 4031.04:

a. The identity of the general licensee by name and address;

b. The type, model number, and serial number of the device received;

c. The date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor; and

d. The identity of the specific licensee submitting the report, including the license number of the specific licensee;

(11) Report to the responsible ~~A~~greement ~~S~~tate or ~~L~~icensing ~~S~~tate agency or the NRC, the identity of the general licensee, the device, and the changes to information on the device label, if the licensee authorized under He-P 4032.03 makes changes to a device possessed by a general licensee authorized under regulations equivalent to He-P 4031.04(b), such that the label must be changed to update required information;

(12) Report to the NRC, if no transfers have been made to or from NRC general licensees during the reporting period;

(13) Report to the ~~A~~greement ~~S~~tate or ~~L~~icensing ~~S~~tate agency or the NRC regulated state if no transfers have been made to or from that ~~A~~greement ~~S~~tate or ~~L~~icensing ~~S~~tate or the NRC regulated state during the reporting period;

(14) Keep records showing:

a. The name of each general licensee or intermediate person to whom transfers of ~~radioactive material~~ byproduct material in devices for use pursuant to the general license provided in He-P 4031.04, or equivalent regulations of the NRC, an ~~A~~greement ~~S~~tate or ~~L~~icensing ~~S~~tate have been made;

b. Address of each general licensee or intermediate person to whom transfers of ~~radioactive material~~ byproduct material in devices for use pursuant to the general license provided in He-P 4031.04, or equivalent regulations of the NRC, an ~~A~~greement ~~S~~tate or ~~L~~icensing ~~S~~tate have been made;

c. The point of contact for each general licensee or intermediate person to whom transfers of ~~radioactive material~~ byproduct material in devices for use pursuant to the general license provided in He-P 4031.04, or equivalent regulations of the NRC, an ~~A~~greement ~~S~~tate or ~~L~~icensing ~~S~~tate have been made;

d. The date of each transfer of ~~radioactive material~~ byproduct material;

e. Identification of the radioisotope contained in each device transferred;

f. The quantity of radioactivity in each device transferred;

g. The identity of any intermediate person; and

h. The requirements of He-P 4031 specifics for this transfer;

(15) Cover each calendar quarter in its reports submitted under He-P 4032;

(16) Submit reports required in He-P 4032.03 within 30 days of the end of the calendar quarter; and

(17) Indicate in reports required in He-P 4032.03, the period covered by the report.

(1) Each person licensed under He-P 4032.03 shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section.

(m) Records required by (l) shall be maintained for a period of 3 years following the date of the recorded event.

He-P 4032.04 Licensing the Introduction of ~~Radioactive Material~~ Byproduct Material Into Products in Exempt Concentrations.

(a) In addition to the requirements in He-P 4030.09, a specific license authorizing the introduction of ~~radioactive material~~ byproduct material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under paragraph He-P 4030.03 shall be issued if:

(1) The applicant submits:

- a. A description of the product or material into which the ~~radioactive material~~ byproduct material will be introduced;
- b. The intended use of the ~~radioactive material~~ byproduct material and the product into which it is introduced;
- c. The method of introduction;
- d. The initial concentration of the ~~radioactive material~~ byproduct material in the product or material;
- e. The control methods to assure that no more than the specified concentration is introduced into the product or material;
- f. The estimated time interval between introduction and transfer of the product or material; and
- g. The estimated concentration of the ~~radioactive material~~ byproduct material ~~in~~ in the product or material at the time of transfer by the licensee; and

(2) The applicant provides ~~reasonable assurance~~ written statements in the application that:

- a. The concentrations of ~~radioactive material~~ byproduct material at the time of transfer will not exceed the concentration in He-P 4093;
- b. That reconcentration of the ~~radioactive material~~ byproduct material in concentrations exceeding those in He-P 4093 is not likely;
- c. That use of lower concentrations is not feasible; and

~~d. That the product or material is~~ shall not ~~likely to~~ be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(b) Each person licensed under He-P 4032.04 shall file an annual report with ~~the~~ DHHS/BRHRHS.

(c) The annual report in (b) above shall:

(1) Identify:

- a. The type and quantity of each product or material into which radioactive material has been introduced during the reporting period;
- b. Name and address of the person who owned or possessed the product or material, into which ~~radioactive material~~byproduct material has been introduced, at the time of introduction;
- c. The type and quantity of radionuclide introduced into each such product or material; and
- d. The initial concentrations of the radionuclide in the product or material at time of transfer of the ~~radioactive material~~byproduct material by the licensee;

(2) Indicate if no transfers of ~~radioactive material~~byproduct material have been made pursuant to He-P 4032.04 during the reporting period;

(3) Cover the year ending June 30; and

(4) Be filed within 30 days thereafter.

He-P 4032.05 Manufacture, Preparation, and-or Distribution of Radiopharmaceuticals Containing ~~Radioactive~~-Byproduct Material for Medical Use-Under Group Licenses.

(a) An application for a specific license to manufacture, prepare, and-or distribute radiopharmaceuticals containing ~~radioactive~~byproduct material for use by persons licensed pursuant to He-P 4035 shall be approved if:

(1) The applicant satisfies the requirements specified in He-P 4030.09;

(2) The applicant submits evidence that the applicant is at least one of the following:

a. Registered or licensed with the U.S. Food and Drug Administration (FDA) as ~~a-the owner or operator of a drug manufacturer~~establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

b. Registered or licensed with a state agency as a drug manufacturer;

c. Licensed as a pharmacy by a State Board of Pharmacy; ~~or~~

d. Operating as a nuclear pharmacy within a federal medical institution; or

e. A Positron Emission Tomography (PET) drug production facility registered with DHHS/RHS.

(3) The applicant submits the following information:

- a. The radionuclide;
- b. The chemical and physical form;
- c. The packaging including maximum activity per ~~package~~ vial, syringe, generator, or other container of the radioactive drug; and
- d. The shielding provided by the packaging of the ~~radioactive material~~ byproduct material shall be appropriate for safe handling and storage of radiopharmaceuticals by group licensees in accordance with He-P 4037.04; and

(4) The applicant satisfies the following labeling requirements:

- a. A label is affixed to each transport radiation shield of a radioactive drug to be transferred for commercial distribution;
- b. The label shall include:
  - 1. The radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL";
  - 2. The name of the radioactive drug or its abbreviation;
  - 3. The quantity of radioactivity at a specified date and time; and
  - 4. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and
- c. A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution.
- d. The label required in He-P-4032.05-(a)(4)c. shall include:
  - 1. The radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; and
  - 2. An identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label; and
- e. The labels, leaflets or brochures required by He-P 4032.03(a)(4) shall be in addition to the labeling required by the Food and Drug Administration (FDA), and shall be separate from or, if approved by the FDA may be combined with, the labeling required by FDA.

(b) A licensee described by He-P 4032.~~04~~.05(a)(2)c. or d.:

- (1) ~~May~~Shall prepare radioactive drugs for medical use, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in He-P 4032.05(b)(2) and (c), or an individual under the supervision of an authorized nuclear pharmacist, as specified in He-P 4035;

- (2) ~~May-Shall~~ allow a pharmacist to work as an authorized pharmacist if:
  - a. This individual qualifies as an authorized nuclear pharmacist as defined in He-P 4035;
  - b. This individual meets the requirements specified in He-P 4035 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or
  - c. This individual is designated as an authorized nuclear pharmacist in accordance with He-P 4032.05(~~eb~~)(3);
- (3) ~~May-Shall~~ designate a pharmacist as defined in He-P ~~4003(ey)~~ 4003.01(df) as an authorized nuclear pharmacist as defined in He-P 4035(c), if: the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the DHHS/BRH under this part.
  - a. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and
  - b. The individual practiced at a pharmacy at a Government agency or ~~Federally~~ federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC;
- (4) Shall provide to ~~the~~ DHHS/BRH-RHS:
  - a. a-A copy of each individual's certification by ~~the Board of Pharmaceutical Specialties~~ a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State as specified in He-P 4035.74(a) with the written attestation signed by a preceptor as required by He-P 4035.74(b)(2); or
  - b. ~~the~~ The U.S. Nuclear ~~Regulatory~~Regulatory Commission or Aagreement Sstate license or Llicensing Sstate license; orlicense; or
  - c. U.S. Nuclear Regulatory Commission master materials licensee permit; or
  - d. The permit issued by a licensee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or
  - e. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission; and-or
  - f. a-A copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows pursuant to He-P 4032.05(b)(2)a. and (b)(2)c., the individual to work as an authorized nuclear pharmacist;

(c) The actions authorized in He-P 4032.05(b)(1) and (b)(2) are permitted in spite of more restrictive language in license conditions.

(d) A licensee authorized under He-P 4032.05 shall:

- (1) Possess and use instrumentation to measure the radioactivity of radioactive drugs;
- (2) Have procedures for use of the instrumentation;
- (3) Measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-, emitting radioactive drugs prior to transfer for commercial distribution; and
- (4) Perform tests before initial use, periodically, and following repair, on each measurement instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and
- (5) Check each measurement instrument for constancy and proper operation at the beginning of each day of use.

(e) Nothing in this section relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

He-P 4032.06 Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing ~~Radioactive Material~~Byproduct Material.

(a) An application for a specific license to manufacture and distribute generators or reagent kits containing ~~radioactive material~~byproduct material or reagent kits not containing ~~radioactive material~~byproduct material used for preparation of radiopharmaceuticals by persons licensed pursuant to He-P 4035 shall be approved if:

- (1) The applicant satisfies the general requirements specified in He-P 4030.09;
- (2) The applicant submits evidence that:
  - a. The generator or reagent kit is to be manufactured, labeled, and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biological product license issued by FDA, or a “Notice of Claimed Investigational Exemption for a New Drug” (IND) that has been accepted by the FDA; or
  - b. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act;
- (3) The applicant submits the following information:
  - a. The radionuclide;

- b. The chemical and physical form;
  - c. The packaging including maximum activity per package; and
  - d. The shielding provided by the packaging of the ~~radioactive material byproduct material~~ contained in the generator or reagent kit;
- (4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and
- (5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:
- a. Radiation safety information on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing ~~radioactive material byproduct material~~ with the reagent kit; and
  - b. A statement that this generator or reagent kit is approved for use by persons licensed by the DHHS/~~BRH~~ RHS pursuant to He-P 4035 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State.

(b) The labels, leaflets, or brochures required by He-P 4032.06(a)(4) and (a)(5) are in addition to the labeling required by FDA and they may be separate from, or if approved by the FDA may be combined with, the labeling required by FDA.

He-P 4032.07 Manufacture and Distribution of Sources or Devices Containing ~~Radioactive Byproduct~~ Material for Medical Use.

(a) An application for a specific license to manufacture and distribute sources and devices containing ~~radioactive byproduct~~ material to persons licensed pursuant to He-P 4035 for use as a calibration, transmission, or reference source, or sources for the uses in Group VI of manual brachytherapy, or sealed sources for diagnosis, or sealed source for the use in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit in accordance with He-P 4035 ~~may~~ shall be approved if:

- (1) The applicant satisfies the general requirements in He-P 4030.09;
- (2) The applicant submits the following radiation safety information for each type of source or device:
  - a. The ~~radioactive byproduct~~ material contained, its chemical and physical form, and amount;
  - b. Details of design and construction of the source or device;
  - c. Procedures for, and results of, prototype tests to demonstrate that the source or device shall maintain its integrity under stresses likely to be encountered in normal use and accidents;

- d. For devices containing ~~radioactive byproduct~~ material, the radiation profile of a prototype device;
- e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
- f. Procedures and standards for calibrating sources and devices;
- g. Legend and methods for labeling sources and devices for their radioactive content; and
- h. Instruction for handling and storing the source or device from the radiation safety standpoint, as follows:
  - 1. These instructions shall be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; or
  - 2. If the instructions are too lengthy for such label, they may be summarized on the label and printed in detail on a brochure which is referenced on the label; and

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains the following information:

- a. The radionuclide;
- b. Quantity;
- c. Date of assay; and
- d. A statement that includes the (name of source or device) which is licensed by ~~the~~ DHHS/BRH-RHS for distribution to persons licensed pursuant to He-P 4035 ~~group VI~~ or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State; and
- ~~e. For sources which do not require long term storage, the label may be on a leaflet or brochure which accompanies the source.~~

(4) The source or device has been registered in the Sealed Source and Device Registry.

(b) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months:

- (1) The application shall include sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(2) In determining the acceptable interval for test of leakage of radioactive material, ~~the~~ DHHS/~~BRH~~ RHS will consider information that includes, but is not limited to:

- a. Primary containment (source capsule);
- b. Protection of primary containment;
- c. Method of sealing containment;
- d. Containment construction materials;
- e. Form of contained radioactive material;
- f. Maximum temperature withstood during prototype tests;
- g. Maximum pressure withstood during prototype tests;
- h. Maximum quantity of contained radioactive material;
- i. Radiotoxicity of contained radioactive material; and
- j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

He-P 4032.08 Special Requirements for the Manufacture, Assembly, ~~or~~ Repair, or initially transfer of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under He-P 4031.02(h) may be approved if:

(a) The applicant satisfies the general requirements specified in He-P 4030.09; and

(b) The applicant satisfies the requirements of 10 CFR 32.53, 32.54, 32.55 and 32.56 ~~and 32.101.~~

He-P 4032.09 Licensing the Distribution of ~~Byproduct Radioactive~~ Material in Exempt Quantities.

(a) An application for specific license to distribute ~~radioactive material~~ byproduct material other than source or byproduct material to persons exempted from licensing pursuant to He-P 4030.08 may be approved if:

(1) The ~~radioactive~~ byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(2) The ~~radioactive~~ byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(3) The applicant submits copies of prototype labels and brochures and ~~the~~ DHHS/~~BRH~~RHS approves such labels and brochures.

(b) The license issued under He-P 4032.09 is subject to the following conditions:

(1) No more than 10 exempt quantities provided the sum of the fractions shall not exceed one which may be composed of fractional parts shall be sold or transferred in any single transaction;

(2) Each exempt quantity shall be separately and individually packaged;

(3) No more than 10 packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to He-P 4030.03;

(4) The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour;

(5) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

a. Identifies the radionuclide and the quantity of radioactivity; and

b. Bears the words "Radioactive Material"; and

(6) In addition to the labeling information required by He-P 4032.09, the label affixed to the immediate container, or an accompanying brochure, shall:

a. State that the contents are exempt from Licensing State requirements;

b. Bear the words "Radioactive Material – Not for Human Use – Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinal, or into Products Manufactured for Commercial Distribution is Prohibited – Exempt Quantities Should Not be Combined"; and

c. Set forth additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the ~~radioactive-byproduct~~ material.

(c) Each person licensed under He-P 4032.09 shall maintain records identifying, by name and address, each person to whom ~~radioactivebyproduct~~ material is transferred for use under He-P 4030.03 or the equivalent rules of an Agreement State or Licensing State, and the kinds and quantities of ~~radioactivebyproduct~~ material transferred.

(d) An annual summary report shall be filed with ~~the~~-DHHS/~~BRH~~RHS, as follows:

(1) Each report shall state the total quantity of each radionuclide transferred under the specific license;

(2) Each report shall cover the year ending June 30;

(3) Each report shall be filed within 30 days after the end of the quarter; and

(4) If no transfers of ~~radioactive-byproduct~~ material have been made pursuant to this section during the reporting period, the report shall so indicate.

He-P 4032.10 Licensing the Incorporation of ~~Radioactive-Byproduct~~ Material Other than Source or Byproduct Material into Gas and Aerosol Detectors.

(a) In addition to the requirements set forth in He-P 4030.09, an application for a specific license authorizing the incorporation of ~~radioactive-byproduct~~ material other than source or byproduct material into gas and aerosol detectors to be distributed to persons exempt under He-P 4030.03 shall only be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26.

(b) The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie.

He-P 4032.11 Special Requirements for License to Manufacture, Import or Initially Distribute Sealed Sources or Devices Containing Sealed Sources to Persons Having a Specific License.

(a) An application for license to ~~manufacture, import (NARM only) or~~ manufacture or initially distribute sealed sources or devices containing sealed sources for initial transfer to persons having a specific license to receive such sealed sources or devices shall be approved subject to the following conditions:

(1) The applicant satisfies the general requirements specified in He-P 4030.09; and

(2) The licensee subject to He-P 4032.11 shall not transfer a sealed source or device containing a sealed source to any person except in accordance with the requirements of He-P 4030.16.

(b) Any manufacturer, ~~importer of NARM~~ or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to ~~the~~ DHHS/~~BRH~~ RHS for evaluation of radiation safety information about its product and for ~~filing an evaluation sheet in the U.S. Department of Health and Human Services "Radioactive Material Reference Manual" or in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices"~~ its registration, as follows:

(1) A request for evaluation of a sealed source or device containing a sealed source shall be submitted in duplicate and shall include information required by He-P 4032.11(b)(2) or (3), as applicable, demonstrating that the radiation safety properties of such source or device will not endanger public health and safety or property;

(2) A request for evaluation of a sealed source shall include the following radiation safety information:

a. Proposed uses for the sealed source;

b. Chemical and physical form and maximum quantity of ~~radioactive-byproduct~~ material in the sealed source;

- c. Details of design of the sealed source, radiation and its shielding including blueprints, engineering drawings or annotated drawings;
- d. Details of construction of the sealed source including a description of materials used in construction;
- e. Radiation profile of a prototype sealed source;
- f. Procedures for and results of prototype testing;
- g. Details of quality control procedures to be followed in manufacture;
- h. A description or facsimile of labeling to be affixed to the sealed source;
- i. Leak testing procedures; and
- j. Any additional information, including experimental studies and tests, required by ~~the~~ DHHS/~~BRH~~ RHS to facilitate a determination of the safety of the sealed source, as required by He-P 4030.09;

(3) A request for evaluation of a device containing a sealed source shall include the following radiation safety information:

- a. Proposed uses for the device;
- b. Manufacturer, model number, chemical and physical form and maximum quantity of radioactivity in the sealed source or sources to be used in the device;
- c. Details of design of the sealed source, including blueprints, engineering drawings or annotated drawings;
- d. Details of construction of the sealed source including a description of materials used in construction;
- e. Radiation profile of a prototype device;
- f. Procedures for and results of prototype testing;
- g. Details of quality control procedures to be followed in manufacture;
- h. A description or facsimile of labeling to be affixed to the device;
- i. Leak testing procedures;
- j. A description of potential hazards in installation, service, manufacture, handling, use, and operation of the device;
- k. Information about installation, service, and maintenance procedures;
- l. Handling, operating, and safety instructions; and

m. Any additional information, including experimental studies and tests, required by ~~the~~ DHHS/~~BRH~~ RHS to facilitate a determination of the safety of the device as required by He-P 4030.09; and

(4) The person submitting a request for evaluation of a product shall manufacture and distribute the product in accordance with:

a. The statements and representations, including the quality control program, described in the request; and

b. The provisions of the evaluation sheet prepared by ~~the~~ DHHS/~~BRH~~ RHS and submitted to the U.S. Department of Health and Human Services, for filing in the "Radioactive Material Reference Manual" or in the U.S. Nuclear Regulatory Commission, for filing in the "Registry of Radioactive Sealed Sources and Devices." and

(5) The request for review shall be mailed to DHHS/RHS office, "ATTN: SDR."

(c) ~~When evaluating a sealed source or device, the DHHS/BRH-RHS will shall apply the radiation safety criteria described in 10 CFR 32.210(d), published January 1, 1993, exclusive of subsequent amendments or editions;~~

(d) After completion of the evaluation, DHHS/RHS shall issue a certificate of registration to the applicant described in 10 CFR 32.210(e);

(e) Authority to manufacture or initially distribute a sealed source or device to specific licensees shall be provided in the license without the issuance of a certificate of registration described in 10 CFR 32.210(g);

(f) After the certificate is issued, DHHS/RHS shall conduct an additional review described in 10 CFR.32.210(h); and

(g) When inactivating certificates of registration of sealed sources and devices, DHHS/RHS shall apply the inactivation criteria described in 10 CFR 32.211.

He-P 4032.12 Prohibition. No person shall introduce ~~radioactive-byproduct~~ material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under He-P ~~4032.12~~4030.03 or equivalent regulations of an Agreement State, the Nuclear Regulatory Commission or Licensing State, except in accordance with a license issued pursuant to He-P 4032.04 or the general license provided in He-P 4030.18.

#### He-P 4032.13 Serialization of Nationally Tracked Sources.

(a) Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

He-P 4032.14 Special Requirements for License to Manufacture or Initially Transfer Calibration Sources Containing Americium-241 or Radium-226 for Distribution to Persons Generally Licensed Under He-P 4031.04(r).

(a) An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 –for distribution to persons generally licensed under He-P 4031.04(r), will be approved if:

(1) The applicant satisfies the general requirements of He-P 4030.09;

(2) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

a. Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

b. Details of construction and design;

c. Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

d. Procedures for and results of prototype testing of sources, which are designed to contain more than 185 becquerel (0.005 microcurie) of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

e. Details of quality control procedures to be followed in manufacture of the source;

f. Description of labeling to be affixed to the source or the storage container for the source; and

g. Any additional information, including experimental studies and tests, required by DHHS/RHS to facilitate a determination of the safety of the source.

(3) Each source will contain no more than 185 kilobecquerel (5 microcurie) of americium-241 or radium-226; and

(4) DHHS/RHS determines, with respect to any type of source containing more than 185 becquerel (0.005 microcurie) of americium-241 or radium-226, that:

a. The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and

b. The source has been subjected to and has satisfactorily passed the appropriate tests prescribed by He-P 4032.14(d).

(b) Each person licensed under He-P 4032.14 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

“The receipt, possession, use and transfer of this source, Model \_\_, Serial No. \_\_, are subject to a general license and the regulations of the DHHS/RHS, the NRC, ~~or~~ an Agreement State, or a Licensing State. Do not remove this label. CAUTION-- RADIOACTIVE MATERIAL-- THIS SOURCE CONTAINS (AMERICIUM-241) OR (RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE (Name of Manufacturer or Transferor).”

(c) Each person licensed under He-P 4032.14 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerel (0.1 microcurie) of americium-241 or radium-226 ~~prior to before~~ transferring the source to a general licensee under He-P 4031.04(r). This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured using methods capable of detecting 185 becquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 185 becquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in He-P 4032(c), the source shall be rejected and shall not be transferred to a general license under He-P 4031.04(r), or equivalent regulations of ~~the NRC, an Agreement State or a licensing state~~;

(d) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source;

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion;

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in He-P 4032.14(d)(4); and

(4) Source designs are rejected for which the following has been detected for any unit: Removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

He-P 4032.15 Manufacture and Distribution of ~~Byproduct~~ Material for Certain In-Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute ~~byproduct~~ material for use under the general license of He-P 4031.06 will be approved if:

(a) The applicant satisfies the general requirements specified in He-P 4030.09;

(b) The radioactive material is to be prepared for distribution in prepackaged units of:

(1) Carbon-14 in units not exceeding 370 kilobecquerel (10 microcurie) each;

(2) Cobalt-57 in units not exceeding 370 kilobecquerel (10 microcurie) each;

(3) Hydrogen-3 (tritium) in units not exceeding 1.85 megabecquerel (50 microcurie) each;

(4) Iodine-125 in units not exceeding 370 kilobecquerel (10 microcurie) each;

(5) Mock Iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 microcurie) of iodine-129 and 185 becquerel (0.005 microcurie) of americium-241 each;

(6) Iodine-131 in units not exceeding 370 kilobecquerel (10 microcurie) each;

(7) Iron-59 in units not exceeding 740 kilobecquerel (20 microcurie) each; and

(8) Selenium-75 in units not exceeding 370 kilobecquerel (10 microcurie) each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kilobecquerel (10 microcurie) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 megabecquerel (50 microcurie) of hydrogen-3 (tritium); 740 kilobecquerel (20 microcurie) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 microcurie) of iodine-129 and 185 becquerel (0.005 microcurie) of americium-241 each; and

(2) Displaying the radiation caution symbol described in He-P 4022.11(c), and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(d) The following statement or a substantially similar statement containing the information called for in the following statement appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

"This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the DHHS/RHS or the NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer)."

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in He-P 4023.01 of these rules.

He-P 4032.16 Ice Detection Devices Containing Strontium-90; Requirements for License to Manufacture or Initially Transfer. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons

generally licensed under U.S. Nuclear Regulatory Commission 10 CFR 31.10 shall be approved if:

(a) The applicant satisfies the general requirements specified in He-P 4030.09; and

(b) The applicant satisfies the requirements of 10 CFR 32.61 and 32.62.

**Readopt with amendment He-P 4033, effective 8-7-07 (Document # 8959), to read as follows:**

PART He-P 4033 SPECIFIC LICENSES OF BROAD SCOPE FOR OTHER THAN HUMAN USE

He-P 4033.01 Purpose. This part shall prescribe requirements for the issuance of specific licenses of broad scope for ~~radioactive~~ byproduct material and certain regulations governing holders of such licenses.

He-P 4033.02 Scope. The provisions and requirements of this part shall be in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of He-P 4030 and U.S. Nuclear Regulatory Commission in 10 CFR Part 37 apply to applications and licenses subject to this part.

He-P 4033.03 Types of Specific Licenses of Broad Scope.

(a) Type A specific license of broad scope shall be a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of a quantity of ~~radioactive~~ byproduct material usually in the multi-curie range specified in the license, but not exceeding quantities specified in the license, for any authorized purpose.

(b) A Type B specific license of broad scope shall be:

(1) A specific license which allows any chemical or physical form of ~~radioactive~~ byproduct material specified in He-P 4033.07, Table 4033.1, for any authorized purpose;

(2) A specific license whereby the possession limit, if only one radionuclide is possessed thereunder, shall be the quantity specified for that radionuclide in He-P 4033.07, Table 4033.1, Column 1; or

(3) A specific license whereby if 2 or more radionuclides are possessed thereunder, the possession limit for each shall be determined as follows:

a. For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in He-P 4033.07, Table 4033.1, Column 1, for that radionuclide; and

b. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(c) A Type C specific license of broad scope shall be:

(1) A specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of ~~radioactive-byproduct~~ material specified in He P 4033.07, Table 4033.1, for any authorized purpose;

(2) A specific license whereby the possession limit, if only one radionuclide, is possessed thereunder, shall be the quantity specified for that radionuclide in He-P 4033.07, Table 4033.1, Column 2; or

(3) A specific license whereby if two or more radionuclides are possessed thereunder, the possession limit shall be determined for each as follows:

a. For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in He-P 4033.07, Table 4033.1, Column 2, for that radionuclide; and

b. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

He-P 4033.04 Application for Specific Licenses of Broad Scope. An application for specific license of broad scope shall be ~~made according to the requirements set forth in He-P 4033.05, filed on a form as described in He P 4004.~~

He-P 4033.05 Requirements for the Issuance of Specific Licenses of Broad Scope.

(a) An application for a Type A specific license of broad scope shall be approved if:

(1) The applicant satisfies the requirements specified in He-P 4030.09;

(2) The applicant has engaged in a reasonable number of activities involving the use of ~~radioactive-byproduct~~ material; and

(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:

a. The establishment of a radiation safety committee composed of such persons as a radiological safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

b. The appointment of a radiological safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters; and

c. The establishment of appropriate administrative procedures to assure:

1. Control of procurement and use of ~~radioactive-byproduct~~ material;

2. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and

equipment, training and experience of the user and the operating or handling procedures; and

3. Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with He-P 4033.05(a)(3)c.2. prior to use of the ~~radioactive~~-byproduct material.

(b) An application for a Type B specific license of broad scope shall be approved if:

(1) The applicant satisfies the general requirements specified in He-P 4030.09; and

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:

a. The appointment of a radiological safety officer who is qualified by training and experience in radiation protection, who is available for advice and assistance on radiological safety matters; and

b. The establishment of appropriate administrative procedures to assure:

1. Control of procurement and use of ~~radioactive~~-byproduct material;

2. Completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and

3. Review, approval and recording by the radiological safety officer of safety evaluations of proposed uses prepared in accordance with He-P 4033.05(b)(2)b.2., prior to use of the ~~radioactive~~-byproduct material.

(c) An application for a Type C specific license of broad scope may be approved if:

(1) The applicant satisfies the requirements specified in He-P 4030.09;

(2) The applicant submits a statement that ~~radioactive~~-byproduct material shall be used only by, or under the direct supervision of, individuals who have received:

a. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

b. At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation doses and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) The applicant has established administrative controls and provisions relating to procurement of ~~radioactive-byproduct~~ material, procedures, record keeping, material control and accounting and management review necessary to assure safety operations.

He-P 4033.06 Conditions of Specific Licenses of Broad Scope.

(a) Unless specifically authorized pursuant to other sections of He-P 4033, persons licensed under this section shall not:

- (1) Conduct tracer studies in the environment involving direct release of ~~radioactive byproduct~~ material;
- (2) Receive, acquire, own, possess, use, transfer, or import devices containing 100,000 curies or more of ~~radioactive-byproduct~~ material in sealed sources to be used for irradiation of materials;
- (3) Conduct activities for which a specific license issued by the DHHS/~~BRHRHS~~ is required; or
- (4) Add or cause the addition of ~~radioactive-byproduct~~ material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(b) Each Type A specific license of broad scope issued by the DHHS/~~BRHRHS~~ shall be subject to the condition that ~~radioactive-byproduct~~ material possessed under the license shall be used only by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(c) Each Type B specific license of broad scope issued by the DHHS/~~BRHRHS~~ shall be subject to the condition that ~~radioactive-byproduct~~ material possessed under the license shall be used only by, or under the direct supervision of, individuals approved by the licensee's radiological safety officer.

(d) Each Type C specific license of broad scope issued by the DHHS/~~BRHRHS~~ shall be subject to the condition that ~~radioactive byproduct~~ material possessed under the license shall be used only by, or under the direct supervision of, individuals who satisfy the requirements of He-P 4033.05(c).

He-P 4033.07 License Quantities for License of Broad Scope. License quantities for licenses of broad scope shall be as described in Table 4033.1.

Table 4033.1 Quantities of ~~Radioactive-Byproduct~~ Material for Licenses of Broad Scope

<del>Radioactive-Byproduct</del> Material	Column 1 (curies)	Column 2 (curies)
Antimony-122	1.0	0.01
Antimony-124	1.0	0.01
Antimony-125	1.0	0.01
Arsenic-73	10.0	0.1
Arsenic-74	1.0	0.01
Arsenic-76	1.0	0.01

<del>Radioactive-Byproduct</del> Material	Column 1 (curies)	Column 2 (curies)
Arsenic-77	10.0	0.1
Barium-131	10.0	0.1
Barium-140	1.0	0.01
Beryllium-7	10.0	0.1
Bismuth-210	0.1	0.001
Bromine-82	10.0	0.1
Cadmium-109	1.0	0.01
Cadmium-115m	1.0	0.01
Cadmium-115	10.0	0.1
Calcium-45	1.0	0.01
Calcium-47	10.0	0.1
Carbon-14	100.0	1.0
Cerium-141	10.0	0.1
Cerium-143	10.0	0.1
Cerium-144	0.1	0.001
Cesium-131	100.0	1.0
Cesium-134m	100.0	1.0
Cesium 134	0.1	0.001
Cesium-135	1.0	0.01
Cesium-136	10.0	0.1
Cesium-137	0.1	0.001
Chlorine-36	1.0	0.01
Chlorine-38	100.0	1.0
Chromium-51	100.0	1.0
Cobalt-57	10.0	0.1
Cobalt-58m	100.0	1.0
Cobalt-58	1.0	0.01
Cobalt-60	0.1	0.001
Copper-64	10.0	0.1
Dysprosium-165	100.0	1.0
Dysprosium-166	10.0	0.1
Erbium-169	10.0	0.1
Erbium-171	10.0	0.1
Europium-152 (9.2 h)	10.0	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1.0	0.01
Fluorine-18	100.0	1.0
Gadolinium-153	1.0	0.01
Gadolinium-159	10.0	0.1
Gallium-72	10.0	0.1
Germanium-71	100.0	1.0
Gold-198	10.0	0.1
Gold-199	10.0	0.1
Hafnium-181	1.0	0.01
Holmium-166	10.0	0.1
Hydrogen-3	100.0	1.0
Indium-113m	100.0	1.0
Indium-114m	1.0	0.01

<del>Radioactive Byproduct</del> Material	Column 1 (curies)	Column 2 (curies)
Indium-115m	100.0	1.0
Indium-115	1.0	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10.0	0.1
Iodine-133	1.0	0.01
Iodine-134	10.0	0.1
Iodine-135	1.0	0.01
Iridium-192	1.0	0.01
Iridium-194	10.0	0.1
Iron-55	10.0	0.1
Iron-59	1.0	0.01
Krypton-85	100.0	1.0
Krypton-87	10.0	0.1
Lanthanum-140	1.0	0.01
Lutetium-177	10.0	0.1
Manganese-52	1.0	0.01
Manganese-54	1.0	0.01
Manganese-56	10.0	0.1
Mercury-197m	10.0	0.1
Mercury-197	10.0	0.1
Mercury-203	1.0	0.01
Molybdenum-99	10.0	0.1
Neodymium-147	10.0	0.1
Neodymium-149	10.0	0.1
Nickel-59	10.0	0.1
Nickel-63	1.0	0.01
Nickel-65	10.0	0.1
Niobium-93m	1.0	0.01
Niobium-95	1.0	0.01
Niobium-97	100.0	1.0
Osmium-185	1.0	0.01
Osmium-191m	100.0	1.0
Osmium-191	10.0	0.1
Osmium-193	10.0	0.1
Palladium-103	10.0	0.1
Palladium-109	10.0	0.1
Phosphorus-32	1.0	0.01
Phosphorus-33	10.0	0.1
Platinum-191	10.0	0.1
Platinum-193m	100.0	1.0
Platinum-193	10.0	0.1
Platinum-197m	100.0	1.0
Platinum-197	10.0	0.1
Polonium-210	0.01	0.0001
Potassium-42	1.0	0.01
Praseodymium-142	10.0	0.1

<del>Radioactive Byproduct</del> Material	Column 1 (curies)	Column 2 (curies)
Praseodymium-143	10.0	0.1
Promethium-147	1.0	0.01
Promethium-149	10.0	0.1
Radium-226	0.01	0.0001
Rhenium-186	10.0	0.1
Rhenium-188	10.0	0.1
Rhodium-103m	1,000.0	10.0
Rhodium-105	10.0	0.1
Rubidium-86	1.0	0.01
Rubidium-87	1.0	0.01
Ruthenium-97	100.0	1.0
Ruthenium-103	1.0	0.01
Ruthenium-105	10.0	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1.0	0.01
Samarium-153	10.0	0.1
Scandium-46	1.0	0.01
Scandium-47	10.0	0.1
Scandium-48	1.0	0.01
Selenium-75	1.0	0.01
Silicon-31	10.0	0.1
Silver-105	1.0	0.01
Silver-110m	0.1	0.001
Silver-111	10.0	0.1
Sodium-22	0.1	0.001
Sodium-24	1.0	0.01
Strontium-85m	1,000.0	10.0
Strontium-85	1.0	0.01
Strontium-89	1.0	0.01
Strontium-90	0.01	0.0001
Strontium-91	10.0	0.1
Strontium-92	10.0	0.1
Sulphur-35	10.0	0.1
Tantalum-182	1.0	0.01
Technetium-96	10.0	0.1
Technetium-97m	10.0	0.1
Technetium-97	10.0	0.1
Technetium-99m	100.0	1.0
Technetium-99	1.0	0.01
Tellurium-125m	1.0	0.01
Tellurium-127m	1.0	0.01
Tellurium-127	10.0	0.1
Tellurium-129m	1.0	0.01
Tellurium-129	100.0	1.0
Tellurium-131m	10.0	0.1
Tellurium-132	1.0	0.01
Terbium-160	1.0	0.01
Thallium-200	10.0	0.1
Thallium-201	10.0	0.1

<del>Radioactive-Byproduct</del> Material	Column 1 (curies)	Column 2 (curies)
Thallium-202	10.0	0.1
Thallium-204	1.0	0.01
Thulium-170	1.0	0.01
Thulium-171	1.0	0.01
Tin-113	1.0	0.01
Tin-125	1.0	0.01
Tungsten-181	1.0	0.01
Tungsten-185	1.0	0.01
Tungsten-187	10.0	0.1
Vanadium-48	1.0	0.01
Xenon-131m	1,000.0	10.0
Xenon-133	100.0	1.0
Xenon-135	100.0	1.0
Ytterbium-175	10.0	0.1
Yttrium-90	1.0	0.01
Yttrium-91	1.0	0.01
Yttrium-92	10.0	0.1
Yttrium-93	1.0	0.01
Zinc-65	1.0	0.01
Zinc-69m	10.0	0.1
Zinc-69	100.0	1.0
Zirconium-93	1.0	0.01
Zirconium-95	1.0	0.01
Zirconium-97	1.0	0.01
Any <del>Radioactive-Byproduct</del> material other than <del>source material,</del> <del>special nuclear material, or</del> alpha emitting <del>radioactive</del> material not listed above.	0.1	0.001

**Readopt with amendment He-P 4034, effective 8-7-07 (Document # 8959), to read as follows:**

**PART He-P 4034 RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS**

He-P 4034.01 Purpose. This part prescribes requirements for the issuance of licenses or registration for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography.

He-P 4034.02 Scope. The requirements of this part are in addition to, and not in substitution for, other requirements of these regulations and cover both radiation machines and sealed ~~radioactive~~ sources containing byproduct material but do not apply to medical uses of ~~sources of radiation~~byproduct material. The requirements and provisions of U.S. Nuclear Regulatory Commission 10 CFR 37 apply to applications and license subject to this part.

He-P 4034.03 Definitions. The following definitions shall apply to this part:

(a) “American National Standards Institute (ANSI)” means the organization that coordinates the development and use of voluntary consensus standards in the United States and represents the needs and views of U.S. stakeholders in standardization forums around the globe.

(b) “Annual refresher safety training” means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography.

(c) “Associated equipment” means equipment that drives, guides, or otherwise comes in contact with the source, when it is used as an exposure head in conjunction with a radiographic exposure device to make radiographic exposures.

(d) “Cabinet radiography” means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for the individual member of the public as the conditions specified in He-P 4020.

(e) “Cabinet x-ray system” ~~or “cabinet”~~ means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor and is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. The term includes “cabinet.” This definition includes x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

(f) “Certifiable cabinet x-ray system” means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

(g) “Certified cabinet x-ray system” means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

(h) “Certifying entity” means an independent certifying organization meeting the requirements in He-P 4034 Appendix A or an Agreement State meeting the requirements in He-P 4034 Appendix A, Parts II and III.

(i) “Collimator” means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

(j) “Control cable” ~~or “drive cable”~~ means the cable that is connected to the source assembly and used to drive the source to and from the exposure location. The term includes “drive cable.”

(k) “Control drive mechanism” means a device that enables the source assembly to be moved into and out of the exposure device.

(l) “Control tube” means a protective sheath which connects the control drive mechanism to the radiographic exposure device for guiding the control cable.

(m) “Exposure head” or “source stop” means a device that locates the gamma radiography sealed source in the selected working position.

(n) “Field station” means a facility from which sources of radiation may be stored or used and from which equipment is dispatched.

(o) “Guide tube” ~~or “projection sheath”~~ means a flexible or rigid, “J”-tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head which may also include the connections necessary for attachment to the exposure device and to the exposure head The term includes “projection sheath.”

(p) “Hands-on experience” means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance.

(q) “Independent certifying organization” means an independent organization that meets all of the criteria of He-P 4034 Appendix A.

(r) “Industrial radiography” ~~or “radiography”~~ means an examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

(s) “Lay-barge radiography” means industrial radiography performed on any water vessel used for laying pipe.

(t) “Offshore platform radiography” means industrial radiography conducted from a platform over a body of water.

(u) “Permanent radiographic installation” means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

(v) “Practical examination” means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

(w) “Radiation safety officer for industrial radiography” means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of He-P 4034.16.

(x) “Radiographer” means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of ~~the~~ DHHS/~~BRH~~ RHS rules and the conditions of the license or the registration.

(y) “Radiographer certification” means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in He-P 4034.17.

(z) “Radiographer’s assistant” means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

(aa) “Radiographic exposure device” or “camera” or “projector” means any instrument containing a source of radiation fastened or contained therein, in which the source of radiation or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

(ab) “Radiographic operations” means all activities performed with a radiographic exposure device, or with a radiation machine to include use, transport performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries.

(ac) “S-tube” means a tube through which the radioactive source travels when inside a radiographic exposure device.

(ad) “Shielded position” means the location within the radiographic exposure device or storage container that, by manufacturer’s design, is the proper location for storage of the sealed source.

(ae) “Source assembly” means an assembly that consists of the sealed source and a connector that attaches the source to the control cable and may include a stop ball to secure the source in the shielded position.

(af) “Source changer” means a device designed and used for replacement of sealed sources in radiographic exposure devices which may also be used for transporting and storing sealed sources.

(ag) “Storage area” means any locked location, facility, or vehicle that is used to store, secure and prevent unauthorized removal of a radiographic exposure device, a radiation machine, or a storage container when it is not used for radiographic operations.

(ah) “Storage container” means a device in which sealed sources or radiation machines are transported or stored.

(ai) “Temporary job site” means a location where radiographic operations are performed and where ~~radioactive-licensed~~ material may be stored other than those location(s) of use authorized on the license or registration certificate.

(aj) “Underwater radiography” means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.

#### He-P 4034.04 Exemptions.

(a) Certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals, are exempt from the requirements of this part except that:

(1) No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit;

(2) Tests for proper operation of interlocks shall be conducted and recorded at intervals not to exceed 6 months;

(3) The registrant shall perform an evaluation to determine compliance with He-P 4020.13(a) through (f), and 21 CFR 1020.40, at intervals not to exceed one year; and

(4) Records of the evaluation required in (a)(1) – (a)(3) above shall be maintained for DHHS/~~BRH~~-RHS inspection until disposal is authorized by ~~the~~-DHHS/~~BRH~~-RHS.

(b) Certified and certifiable cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 and no modification shall be made to the system unless prior DHHS/~~BRH~~-RHS approval has been granted.

(c) Industrial uses of hand-held light intensified imaging devices are exempt from the regulations in this part if the exposure level 18 inches from the source of radiation to any individual does not exceed 2 millirem per hour.

(d) Industrial uses of hand-held light intensified imaging devices with exposure levels that exceed the 2 millirem per hour level shall meet the applicable requirements of this part and He-P 4040 or He-P 4030, as applicable.

He-P 4034.05 Licensing and Registration Requirements for Industrial Radiography Operations. ~~The~~-DHHS/~~BRH~~-RHS shall approve an application for a specific license for the use of radioactive-licensed material or a registration for use of radiation machines if:

(a) The applicant or registrant satisfies the general requirements specified in He-P 4040 for radiation machine facilities or He-P 4030 for radioactive-byproduct material, and any special requirements contained in this part;

(b) The applicant submits a program for training radiographers and radiographers' assistants that meets the requirements of He-P 4034.17:

(c) The applicant or registrant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

(d) The applicant or registrant submits written operating and emergency procedures as described in He-P 4034.18~~17~~(g);

(e) The applicant or registrant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months as described in He-P 4034.17(e);

(f) The applicant or registrant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

(g) The applicant or registrant submits the qualifications of the individual(s) designated as the Radiation Safety Officer as described in He-P 4034.16;

(h) An applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, or intends to analyze their own wipe samples, the applicant describes the procedures for performing these tests to include:

- (1) Methods of collecting the samples;
- (2) Qualifications of the individual who analyzes the samples;
- (3) Instruments to be used; and
- (4) Methods of analyzing the samples;

(i) The applicant or registrant intends to perform calibrations of survey instruments and alarming rate-meters, the applicant describes methods to be used and the experience of the person(s) who will perform the calibrations;

(j) All calibrations of survey instruments and alarming ratemeters are performed according to the procedures described and at the intervals prescribed in He-P 4034.09 and He-P 4034.20(p)(4);

(j) The applicant or registrant identifies and describes the location(s) of all field stations and permanent radiographic installations;

(k) The applicant or registrant identifies the locations where all records required by this and other parts of these regulations will be maintained;

(l) A license application or radiation machine use includes underwater radiography, a description of the following is included:

- (1) Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;
- (2) Radiographic equipment and radiation safety equipment unique to underwater radiography; and
- (3) Methods for gas-tight encapsulation of equipment; ~~and~~

(m) An application or radiation machine use includes offshore platform and/or lay-barge radiography, a description of the following is included:

- (1) Transport procedures for ~~radioactive material~~ sealed source to be used in industrial radiographic operations;
- (2) Storage facilities for ~~radioactive material~~ sealed source; and
- (3) Methods for restricting access to radiation areas; and

(n) Each registrant complies with the requirements, as appropriate, of He-P 4034.04 for use of radiation machines in industrial radiographic operations.

He-P 4034.06 Performance Requirements for Industrial Radiography Equipment. Equipment used in industrial radiographic operations shall meet the following minimum criteria:

(a) Each radiographic exposure device, source assembly or sealed source, and all associated equipment shall meet the requirements specified in American National Standard Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981) which is incorporated by reference and included in Appendix C.

(b) In addition to the requirements specified in He-P 4034.06(a), the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(1) The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

- a. Chemical name or symbol and mass number of the radionuclide in the device;
- b. Activity and the date on which this activity was last measured;
- c. Model or product code and serial number of the sealed source;
- d. Manufacturer's identity of the sealed source; and
- e. Licensee's name, address, and telephone number;

(2) Radiographic exposure devices intended for use as Type B transport containers shall meet the applicable requirements of He-P 4037; and

(3) Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system and such modifications have been approved by ~~the~~ DHHS/BRHRHS;

(c) In addition to the requirements specified in He-P 4034.06(a) and (b) of this section, the following requirements shall apply to radiographic exposure devices, source assemblies, source changers, and associated equipment that allow the source to be moved out of the device for radiographic operations:

(1) The coupling between the source assembly and the control cable shall be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions;

(2) The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device;

(3) This securing system required in He-P 4034.06(c)(2) shall only be released by means of a deliberate operation on the exposure device;

- (4) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers which must be installed during storage and transportation;
  - (5) Each sealed source or source assembly shall have attached to it or engraved on it, a durable, legible, visible label with the words: "DANGER -- RADIOACTIVE";
  - (6) The label required in He-P 4034.05(c)(5) shall not interfere with the safe operation of the exposure device or associated equipment;
  - (7) The guide tube shall:
    - a. Be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use; and
    - b. Be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use;
  - (8) Guide tubes shall be used when moving the source out of the device;
  - (9) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during industrial radiography operations;
  - (10) The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432-1980; and
  - (11) Source changers shall provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly;
- (d) All radiographic exposure devices and associated equipment in use after January 10, 1996, shall comply with the requirements of He-P 4034.06; and
- (e) Notwithstanding He-P 4034.06(a), equipment used in industrial radiographic operations ~~may~~ shall not be required to comply with "I 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980," as referenced in 10 CFR 34.20, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

He-P 4034.07 Limits on External Radiation Levels from Storage Containers and Source Changers. The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

He-P 4034.08 Locking of Radiographic Exposure Devices, Storage Containers and Source Changers.

(a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position.

(b) The exposure device and/or its container shall be kept locked, with key removed if applicable, when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in He-P 4034.22.

(c) During radiographic operations the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(d) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position.

(e) Storage containers and source changers shall be kept locked with key removed if applicable, when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(f) The control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation.

(g) The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

He-P 4034.09 Radiation Survey Instruments.

(a) The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this part and by He-P 4022.

(b) Instrumentation required by He-P 4034.09(a) shall be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

(c) The licensee or registrant shall have each radiation survey instrument required under He-P 4034.09(a) calibrated:

(1) At energies appropriate for use and at intervals not to exceed 6 months or after instrument servicing, except for battery changes;

(2) For linear scale instruments, at 2 points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at 2 points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1,000 mrem) per hour; and

(3) So that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point checked.

(d) The licensee shall maintain records of the results of the instrument calibrations in accordance with He-P 4034.26.

He-P 4034.10 Leak Testing and Replacement of Sealed Sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source shall be performed by persons authorized to do so by ~~the~~-DHHS/BRHRHS, the U.S. Nuclear Regulatory Commission, or another Agreement State.

(b) The opening, repair, or modification of any sealed source shall be performed by persons specifically authorized to do so by ~~the~~-DHHS/BRHRHS, the NRC, or another Agreement State.

(c) Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months.

(d) The leak testing of a sealed source shall include:

(1) A method approved by ~~the~~-DHHS/BRHRHS, the NRC, or by another Agreement State;

(2) A wipe sample taken from the nearest accessible point to the sealed source where contamination might accumulate;

(3) An analysis of the wipe sample for radioactive contamination which is capable of detecting the presence of 185 becquerel (0.005  $\mu$ Ci) of radioactive material on the test sample; and

(4) Performance of the wipe sample by a person specifically authorized by ~~the~~ DHHS/BRHRHS, the NRC, or another Agreement State.

(e) The licensee shall maintain records of the leak tests in accordance with He-P 4034.27.

(f) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it shall not be used by the licensee until tested for leakage.

(g) Sealed sources that are in storage and not in use shall not require leak testing.

(h) Sealed sources that are in storage and not in use shall be tested before use or transfer to another person if the interval of storage exceeds 6 months.

(i) Any test conducted pursuant to He-P 4034.10 that reveals the presence of 185 becquerel (0.005  $\mu$ Ci) or more of removable radioactive material shall be considered evidence that the sealed source is leaking.

(j) If a sealed source is found to be leaking, the licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with He-P 4000.

(k) If a sealed source is found to be leaking, a report must be filed with ~~the~~-DHHS/BRHRHS within 5 days of the test, describing the equipment involved, the test results, and the corrective action taken.

(l) Each exposure device using depleted uranium (DU) shielding and an S-tube configuration shall:

- (1) Be tested for DU contamination at intervals not to exceed 12 months;
- (2) Be analyzed by a method capable of detecting the presence of 185 becquerel (0.005  $\mu$ Ci) of radioactive material on the test sample; and
- (3) Have the test performed by a person specifically authorized by ~~the~~ DHHS/~~BRH~~RHS, the NRC, or another Agreement State to perform the analysis.

(m) Should the testing required in He-P 4034.10(l) reveal the presence of DU contamination, the exposure device shall be removed from use until an evaluation of the wear of the S-tube has been made.

(n) Should the evaluation in He-P 4034.10(m) reveal that the S-tube is worn through, the device shall not be used again.

(o) DU shielded devices shall not have to be tested for DU contamination while in storage and not in use.

(p) Before using or transferring a DU device, the device shall be tested for DU contamination if the interval of storage exceeds 12 months.

(q) A record of the DU leak-test shall be made in accordance with He-P 4034.27.

He-P 4034.11 Quarterly Inventory.

(a) Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation and for all devices containing depleted uranium which have been received and possessed under the license.

(b) The licensee or registrant shall maintain records of the quarterly inventory in accordance with He-P 4034.27.

He-P 4034.12 Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers at the start of each days use, or work shift, to ensure that:

- (1) The equipment is in good working condition;
- (2) The sources are adequately shielded; and
- (3) Required labeling is present.

(b) Survey instrument operability shall be performed using check sources or other appropriate means.

(c) Each licensee or registrant shall conduct a program for inspection and maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety is in accordance with manufacturer's specifications.

(d) Each licensee or registrant shall ensure that all replacement components for radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers and survey instruments meet design specifications.

(e) If any equipment problems are found, the equipment shall be removed from service and labeled as defective until repaired.

(f) The licensee's inspection and maintenance program shall include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of registration.

(g) Records of equipment problems and of any maintenance performed under He-P 4034.12 shall be made in accordance with He-P 4034.30.

He-P 4034.13 Permanent Radiographic Installations.

(a) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall be equipped with:

(1) An entrance control of the type described in He-P 4022.04 that causes the radiation level upon entry into the area to be reduced; or

(2) Conspicuous visible and audible warning signals to warn of the presence of radiation as follows:

a. The visible signal must be actuated by radiation whenever the source is exposed or the machine is energized; and

b. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

(b) The alarm system described in He-P 4034.13(a)(2) shall be tested for proper operation of both the visible and audible signals, with a radiation source, each day before the installation is used for radiographic operations.

(c) Entrance control devices that reduce the radiation level upon entry as designated in He-P 4034.13(a)(1) shall be tested monthly.

(d) If an entrance control device or an alarm is not operating properly, it shall be immediately labeled as defective and repaired within 7 calendar days.

(e) An installation with a defective entrance control device or an alarm may continue to be used for a 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of He-P 4034.22 and an alarming ratemeter is used.

(f) Test records for entrance controls and audible and visual alarms shall be maintained in accordance with He-P 4034.31.

He-P 4034.14 Labeling, Storage, and Transportation.

(a) The licensee shall not use a source changer or a container to store ~~radioactive material~~licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, having a minimum diameter of 25mm and the wording:

“CAUTION [or “DANGER”]  
RADIOACTIVE MATERIAL  
NOTIFY CIVIL AUTHORITIES [or “NAME OF COMPANY”]”

(b) The licensee shall not transport ~~radioactive-licensed~~ material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with He-P 4037.

(c) Radiographic exposure devices, source changers, storage containers, and radiation machines, shall be physically secured to prevent tampering or removal by unauthorized personnel.

(d) The licensee shall store ~~radioactive-byproduct~~ material in a manner that will minimize danger from explosion or fire.

(e) The licensee shall lock and physically secure the transport package containing ~~radioactive-licensed~~ material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(f) The licensee’s or registrant’s name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all vehicles used to transport ~~radioactive-licensed~~ material or radiation machines for temporary job site use.

He-P 4034.15 Conducting Industrial Radiographic Operations.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the following shall be required:

(1) The radiographer shall be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of He-P 4034.17;

(2) The second qualified individual on site shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry into the restricted area; and

(3) Radiography shall not be performed if only one qualified individual is present.

(b) All radiographic operations shall be conducted in a permanent radiographic installation unless otherwise specifically authorized by ~~the~~ DHHS/~~BRH~~RHS.

(c) Collimators shall be used in industrial radiographic operations that use crank-out devices except when physically impossible.

(d) A licensee or registrant shall conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by ~~the~~ DHHS/~~BRH~~RHS, the Nuclear Regulatory Commission, or another Agreement State.

He-P 4034.16 Radiation Safety Officer.

(a) The Radiation Safety Officer (RSO) shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

(b) The minimum qualifications, training, and experience for RSOs for industrial radiography shall be as follows:

(1) Completion of the training and testing requirements of He-P 4034.17(a).

(2) 2,000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(3) Formal training in the establishment and maintenance of a radiation protection program.

(c) In lieu of (b), a licensee may apply to ~~the~~ DHHS/~~BRH~~RHS for approval of an individual to serve as RSO, when such individual has appropriate training and/or experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(d) The specific duties and authorities of the RSO shall include, but shall not be limited to:

(1) Establishing and overseeing all operating, emergency, and ALARA procedures as required by He-P 4020 through He-P 4023 and reviewing these procedures regularly to ensure that they conform to DHHS/~~BRH~~RHS rules and the license or registration conditions;

(2) Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;

(3) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with He-P 4034, including any corrective measures when levels of radiation exceed established limits;

(4) Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly;

- (5) Ensuring that records are kept of the personnel monitoring results;
- (6) Ensuring that timely notifications are made as required by He-P 4021.13; and
- (7) Ensuring that working operations are conducted safely, that corrective actions are implemented, and that unsafe operations are terminated.

He-P 4034.17 Training.

(a) The licensee or registrant shall not permit any individual to act as a radiographer until the individual:

- (1) Has received 40 hours of training in the subjects in He-P 4034.17(h) in addition to a minimum of 2 months of on-the-job training;
- (2) Is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in He-P 4034 Appendix A; and
- (3) Has received training in the subjects outlined in He-P 4034.17(h) and demonstrated an understanding of these subjects by successful completion of a written examination.

(b) In addition to (a) above, the licensee or registrant shall not permit any individual to act as a radiographer until the individual:

- (1) Has received copies of, and instruction in the requirements described in, the rules contained in this part, and applicable sections of He-P 4019 through He-P 4023 and He-P 4037, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;
- (2) Has demonstrated an understanding of items in He-P 4034.17(b)(1) by successful completion of a written or oral examination;
- (3) Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and
- (4) Has demonstrated understanding of the use of the equipment described in He-P 4034.17(b)(1) and (b)(3) by successful completion of a practical examination.

(c) The licensee shall not permit any individual to act as a radiographer's assistant until the individual:

- (1) Has received copies of, and instruction in the requirements described in, the rules contained in this part, and applicable sections of He-P 4019 through He-P 4023 and He-P 4037, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

(2) Has demonstrated an understanding of items in He-P 4034.17(c)(1) by successful completion of a written or oral examination;

(3) Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(4) Has demonstrated understanding of the use of the equipment described in He-P 4034.17(c)(3) by successful completion of a practical examination.

(d) The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(e) Except as provided in He-P 4034.17(f)(3)b., the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that ~~the~~ DHHS/~~BRH~~ RHS rules, license or registration requirements, and operating and emergency procedures are followed.

(f) The inspection program required in He-P 4034.17(e) shall:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer shall demonstrate knowledge of the training requirements of He-P 4034.17(b)(3) and the radiographer's assistant must demonstrate knowledge of the training requirements of He-P 4034.17(c)(3) by a practical examination before these individuals can next participate in a radiographic operation;

(3) Except that:

a. ~~The~~ DHHS/~~BRH~~ RHS may consider alternatives in those situations where the individual serves as both radiographer and RSO; and

b. In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

(g) The licensee or registrant shall maintain records of all required training, to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with He-P 4034.31.

(h) The licensee or registrant shall include the following subjects in the training program required in He-P 4034.16(b):

(1) Fundamentals of radiation safety including:

a. Characteristics of gamma radiation;

- b. Units of radiation dose and quantity of radioactivity;
- c. Hazards of exposure to radiation;
- d. Levels of radiation from sources of radiation; and
- e. Methods of controlling radiation dose (time, distance, and shielding);

(2) Radiation detection instruments including:

- a. Use, operation, calibration, and limitations of radiation survey instruments;
- b. Survey techniques; and
- c. Use of personnel monitoring equipment;

(3) Equipment to be used including:

- a. Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtailed);
- b. Operation and control of radiation machines;
- c. Storage, control, and disposal of sources of radiation; and
- d. Inspection and maintenance of equipment;

(4) The requirements of this chapter and pertinent regulations in the Code of Federal Regulations; and

(5) Case histories of accidents in radiography.

He-P 4034.18 Operating and Emergency Procedures.

(a) Operating and emergency procedures shall include, as a minimum, instructions in the following:

- (1) Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in He-P 4020;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods for posting and controlling access to radiographic areas;
- (4) Methods and occasions for locking and securing sources of radiation;
- (5) Personnel monitoring and the use of personnel monitoring equipment;

(6) Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as required in He-P 4037;

(7) The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers;

(8) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming rate-meter alarms unexpectedly;

(9) The procedure(s) for identifying and reporting defects and noncompliance, as required by He-P 4034.37;

(10) The procedure for notifying proper persons in the event of an accident or incident;

(11) Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;

(12) Source recovery procedure if licensee will perform source recovery; and

(13) Maintenance of records.

(b) The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with He-P 4034.33 and He-P 4034.37.

He-P 4034.19 Supervision of Radiographers' Assistants.

(a) The radiographer's assistant shall be under the personal supervision of a radiographer when using sources of radiation or conducting radiation surveys required by He-P 4034.21(b) to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure.

(b) The personal supervision required in He-P 4034.19(a) shall include:

(1) The radiographer's physical presence at the site where the sources of radiation are being used;

(2) The availability of the radiographer to give immediate assistance if required; and

(3) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

He-P 4034.20 Personnel Monitoring.

(a) The licensee or registrant shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an alarming ratemeter, and

either a film badge~~or~~, a thermoluminescent dosimeter (TLD) or an optically stimulated luminescence dosimeter (OSL).

(b) At permanent radiography installations where alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the wearing of an alarming ratemeter is not required.

(c) Pocket dosimeters shall:

- (1) Have a range from zero to 2 millisieverts (200 mrem); and
- (2) Be recharged at the start of each shift.

(d) Electronic personal dosimeters shall only be used in place of ion-chamber pocket dosimeters.

(e) Each film badge~~and~~, TLD and OSL shall be assigned to and worn by only one individual.

(f) Film badges~~and~~, TLDs and OSLs shall be exchanged at periods not to exceed one month.

(g) After replacement, each film badge~~or~~, TLD or OSL shall be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable.

(h) In circumstances that make it impossible to return each film badge~~or~~, TLD or OSL within 14 calendar days, such circumstances shall be documented and available for review by ~~the~~ DHHS/BRHRHS.

(i) Direct reading dosimeters, such as pocket dosimeters or electronic personal dosimeters, shall:

- (1) Be read at the beginning and end of each shift;
- (2) Have the exposures recorded at the beginning and end of each shift; and
- (3) Be recorded in records maintained in accordance with He-P 4034.34.

(j) Pocket dosimeters, or electronic personal dosimeters, shall be checked at periods not to exceed 12 months in order to verify that readings are within plus or minus 20 percent of the true radiation exposure.

(k) Records resulting from the check of pocket dosimeters or electronic personal dosimeters shall be maintained in accordance with He-P 4034.34.

(l) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 millisieverts (200 mrem):

- (1) The individual's film badge or TLD shall be sent for processing within 24 hours;

(2) The individual shall not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made by the RSO or the RSO's designee; and

(3) The results of this determination shall be included in the records maintained in accordance with He-P 4034.34.

~~(m) If a film badge or~~ TLD or OSL is lost or damaged, the worker shall cease work immediately until a replacement film badge ~~or~~ TLD or OSL is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge ~~or~~ TLD or OSL.

(n) The results of the calculated exposure required in He-P 4034.19(m) and the time period for which the film badge was lost or damaged shall be included in the records maintained in accordance with He-P 4034.33.

(o) Reports received from the film badge ~~or~~ TLD or OSL processor shall be retained in accordance with He-P 4034.34.

(p) Each alarming ratemeter shall:

(1) Be checked to ensure that the alarm functions properly before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of 5 millisieverts per hour (500 ~~m~~mrem/hr), with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(3) Require special means to change the preset alarm function;

(4) Be calibrated at periods not to exceed 12 months for correct response to radiation; and

(5) Have its calibration history maintained by the licensee in accordance with He-P 4034.34.

He-P 4034.21 Radiation Surveys. The licensee or registrant shall:

(a) Conduct surveys with a calibrated and operable radiation survey instrument that meets the requirements of He-P 4034.09;

(b) Using a survey instrument meeting the requirements of He-P 4034.21(a), conduct a survey of the radiographic exposure device and the guide tube in order to determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment;

(c) Survey radiation machines after each exposure to determine that the machine is off;

(d) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument whenever the source is exchanged and whenever a radiographic exposure

device is placed in a storage area as defined in He-P 4003.01(~~ezfi~~), to ensure that the sealed source is in its shielded position; and

(e) Maintain records in accordance with He-P 4034.35.

He-P 4034.22 Surveillance. During each radiographic operation, the radiographer shall ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in He-P 4003.01(~~dxde~~) and (~~btbw~~), respectively, except at permanent radiographic installations where all entryways are locked and the requirements of 4034.13 are met.

He-P 4034.23 Posting.

(a) All areas in which industrial radiography is being performed shall be conspicuously posted as required by He-P 4022.11.

(b) The exceptions listed in He-P 4022.12 of this chapter do not apply to industrial radiographic operations.

~~He-P 4034.24~~ Records for Industrial Radiography. Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by ~~the~~ DHHS/~~BRH~~RHS, or until ~~the~~ DHHS/~~BRH~~RHS terminates the license or registration.

He-P 4034.25 Records of Receipt and Transfer of Sources of Radiation.

(a) Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for 3 years after it is made.

(b) These records shall include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

He-P 4034.26 Records of Radiation Survey Instruments. Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under He-P 4034.09 and retain each record for 3 years after it is made.

He-P 4034.27 Records of Leak Testing of Sealed Sources and Devices Containing DU.

(a) Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU in units of becquerels (mCi).

(b) The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

He-P 4034.28 Records of Quarterly Inventory.

(a) Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by He-P 4034.11, and retain each record for 3 years.

(b) The record shall include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

He-P 4034.29 Utilization Logs.

(a) Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

- (1) A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;
- (2) The identity or signature of the radiographer to whom assigned;
- (3) The location and dates of use, including the dates removed and returned to storage; and
- (4) For permanent radiographic installations, the dates each radiation machine is energized.

(b) The licensee or registrant shall retain the logs required by He-P 4034.29(a) for 3 years.

He-P 4034.30 Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) Each licensee or registrant shall maintain records specified in He-P 4034.12 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

(b) The record shall include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

He-P 4034.31 Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations. Each licensee or registrant shall maintain records of alarm system and entrance control device tests required by He-P 4034.13 and retain each record for 3 years after it is made.

He-P 4034.32 Records of Training and Certification. Each licensee or registrant shall maintain the following records for each radiographer and each radiographer's assistant for 3 years:

(a) Records of training to include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations;

(b) Records of annual refresher safety training to include a list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees; and

(c) Records of semi-annual inspections of job performance to include a list showing the items checked and any non-compliance observed by the RSO.

He-P 4034.33 Copies of Operating and Emergency Procedures.

(a) Each licensee or registrant shall maintain a copy of current operating and emergency procedures until ~~the~~ DHHS/BRH-RHS terminates the license or registration.

(b) Superseded material in the operating and emergency procedures shall be retained for 3 years after the change is made.

He-P 4034.34 Records of Personnel Monitoring. Each licensee or registrant shall maintain the following exposure records specified in He-P 4034.20:

(a) Direct reading dosimeter readings and yearly operability checks required by He-P 4034.20(i) and (j) for 3 years after the record is made;

(b) Records of alarming ratemeter calibrations for 3 years after the record is made;

(c) Reports received from the film badge-~~or~~, TLD or OSL processor until ~~the~~ DHHS/BRH-RHS terminates the license or registration; and

(d) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges-~~or~~, TLDs or OSLs, until ~~the~~ DHHS/BRH-RHS terminates the license or registration.

He-P 4034.35 Records of Radiation Surveys.

(a) Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in He-P 4034.21(c).

(b) Each record shall be maintained for 3 years after it is made.

He-P 4034.36 Form of Records.

(a) Each record required by He-P 4034 shall be legible throughout the specified retention period.

(b) The record shall be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by an individual authorized by the registrant or licensee and that the microform is capable of reproducing a clear copy throughout the required retention period.

(c) The record ~~shall~~may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period, if electronic media is available.

(d) Records, such as letters, drawings, and specifications, shall include ~~all-pertinent~~ information, such as stamps, initials, and signatures.

(e) The licensee or registrant shall maintain ~~adequate~~-safeguards against tampering with and loss of records.

He-P 4034.37 Location of Documents and Records.

(a) Each licensee or registrant shall maintain copies of records required by He-P 4034 and other applicable parts of these rules at the location specified in He-P 4034.05(k).

(b) Each licensee or registrant shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary job site:

- (1) The license or registration authorizing the use of sources of radiation;
- (2) A copy of He-P 4003, He-P 4019 through He-P 4023, and He-P 4034;
- (3) Utilization records for each source of radiation dispatched from that location as required by He-P 4034.29;
- (4) Records of equipment problems identified in daily checks of equipment as required by He-P 4034.30(a);
- (5) Records of alarm system and entrance control checks required by He-P 4034.31, if applicable;
- (6) Records of dosimeter readings as required by He-P 4034.34;
- (7) Operating and emergency procedures required by He-P 4034.33;
- (8) Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by He-P 4034.26;
- (9) Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by He-P 4034.34;
- (10) Survey records as required by He-P 4034.35 and He-P 4021.03 as applicable, for the period of operation at the site;
- (11) The shipping papers for the transportation of radioactive materials required by He-P 4037; and
- (12) When operating under reciprocity pursuant to He-P 4030.17, a copy of the Agreement State license or registration, or NRC license authorizing the use of sources of radiation.

He-P 4034.38 Notifications.

(a) In addition to the reporting requirements specified in He-P 4021, each licensee or registrant shall provide a written report to ~~the~~ DHHS/~~BRH~~ RHS within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

- (1) Unintentional disconnection of the source assembly from the control cable;
- (2) Inability to retract the source assembly to its fully shielded position and secure it in this position;
- (3) Failure of any component, which is critical to safe operation of the device, to properly perform its intended function;
- (4) Failure of an indicator on a radiation machine to show that radiation is being produced;
- (5) Failure of an exposure switch to terminate production of radiation when switched to the off position; and
- (6) Failure of a safety interlock to terminate x-ray production.

(b) The licensee or registrant shall include the following information in each report submitted under He-P 4034.38(a), and in each report of overexposure submitted under He-P 4021.14 which involves failure of safety components of radiography equipment:

- (1) Description of the equipment problem;
- (2) Cause of each incident, if known;
- (3) Name of the manufacturer and model number of equipment involved in the incident;
- (4) Place, date, and time of the incident;
- (5) Actions taken to establish normal operations;
- (6) Corrective actions taken or planned to prevent recurrence; and
- (7) Names and qualifications of personnel involved in the incident.

(c) Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, shall notify ~~the~~ DHHS/~~BRH~~ RHS prior to exceeding the 180 days.

He-P 4034.39 Specific Requirements for Radiographic Personnel Performing Industrial Radiography.

(a) At a job site, the following shall be supplied by the licensee or registrant:

- (1) At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

(2) A current whole body individual monitoring device (~~TLD or~~ film badge, TLD or OSL) for each worker;

(3) An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each worker;

(4) An operable, calibrated, alarming rate-meter for each worker; and

(5) The appropriate barrier ropes and caution signs.

(b) Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

(c) Industrial radiographic operations shall not be performed if any of the items in He-P 4034.39(a) are not available at the job site or are inoperable.

(d) During an inspection, ~~the~~ DHHS/BRH-RHS shall terminate an operation if any of the items in He-P 4034.39(a) are not available or operable, or if the required number of radiographic personnel is not present.

(e) Operations terminated under the conditions of He-P 4034.39(d) shall not be resumed until all required conditions are met.

He-P 4034

## APPENDIX A

### I. Requirements for an Independent Certifying Organization.

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;
2. Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;
3. Have a certification program open to nonmembers, as well as members;
4. Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;
5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;
6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;
8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;
9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification, and the administration of its certification program;
10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;
11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly owned subsidiary of such company or corporation) as any of the examinees;
12. Exchange information about certified individuals with the Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and
13. Provide a description to the Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

## II. Requirements for Certification Programs.

All certification programs shall:

### 1. Require applicants for certification to:

(a) Receive training in the topics set forth in He-P 4034.17(h) or equivalent Agreement State or Nuclear Regulatory Commission regulations; and

(b) Satisfactorily complete a written examination covering these topics;

### 2. Require applicants for certification to provide documentation that demonstrates that the applicant has:

(a) Received training in the topics set forth in He-P 4034.17(h) or equivalent Agreement State or NRC regulations;

(b) Satisfactorily completed a minimum period of on-the-job training; and

(c) Received verification by an Agreement State licensee or registrant or a NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;

### 3. Include procedures to ensure that all examination questions are protected from disclosure;

### 4. Include procedures for denying an application and, revoking, suspending, and reinstating a certification;

### 5. Provide a certification period of not less than 3 years nor more than 5 years;

### 6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

### 7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

## III. Requirements for Written Examinations

All examinations shall be:

### 1. Designed to test an individual's knowledge and understanding of the topics listed in He-P 4034.17(h) or equivalent Agreement State or NRC requirements;

### 2. Written in a multiple-choice format; and

### 3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in He-P 4034.17(h).

APPENDIX B

Rule	RSA or Federal Regulation Implemented
He-P 4032	Section 274 of the AEA of 1954, as amended, and Title 10 CFR Part 32
He-P 4032.01	10 CFR 32.1
He-P 4032.02	10 CFR 32.1(b)
He-P 4032.03	10 CFR 32.51
He-P 4032.04	10 CFR 32.11
He-P 4032.05	10 CFR 32.72
He-P 4032.06	10 CFR 32.72
He-P 4032.07	10 CFR 32.74
He-P 4032.08	10 CFR 32.53
He-P 4032.09	10 CFR 32.18
He-P 4032.10	10 CFR 32.26
He-P 4032.11	10 CFR 32.14
He-P 4032.12	10 CFR 32.13
He-P 4032.13	10 CFR 32.201
He-P 4032.14	10 CFR 32.57
He-P 4032.15	10 CFR 32.51
He-P 4032.16	10 CFR 32.61, 10 CFR 32.62
He-P 4033	Section 274 of the AEA of 1954, as amended, and Title 10 CFR Part 33
He-P 4033.01	10 CFR 33.1
He-P 4033.02	10 CFR 33.1
He-P 4033.03	10 CFR 33.11
He-P 4033.04	10 CFR 33.12
He-P 4033.05	10 CFR 33.13, 33.14, 33.15
He-P 4033.06	10 CFR 33.17
He-P 4033.07	10 CFR 33.100, Schedule A
He-P 4034	Section 274 of the AEA of 1954, as amended, and Title 10 CFR Part 34; Title 21 CFR Part 1020
He-P 4034.01	10 CFR 34.1
He-P 4034.02	10 CFR 34.1
He-P 4034.03	10 CFR 34.3, 21 CFR 1020.40
He-P 4034.04	10 CFR Part 34, Subpart G (10 CFR 34.111); 21 CFR 1020.40
He-P 4034.05	10 CFR Part 34.11, 34.13
He-P 4034.06	10 CFR 34.20
He-P 4034.07	10 CFR 34.21
He-P 4034.08	10 CFR 34.23
He-P 4034.09	10 CFR 34.25
He-P 4034.10	10 CFR 34.27
He-P 4034.11	10 CFR 34.29
He-P 4034.12	10 CFR 34.31
He-P 4034.13	10 CFR 34.33
He-P 4034.14	10 CFR 34.35
He-P 4034.15	10 CFR 34.41
He-P 4034.16	10 CFR 34.42
He-P 4034.17	10 CFR 34.43

He-P 4034.18	10 CFR 34.45
He-P 4034.19	10 CFR 34.46
He-P 4034.20	10 CFR 34.47
He-P 4034.21	10 CFR 34.49
He-P 4034.22	10 CFR 34.51
He-P 4034.23	10 CFR 34.53
He-P 4034.24	10 CFR 34.61
He-P 4034.25	10 CFR 34.63
He-P 4034.26	10 CFR 34.65
He-P 4034.27	10 CFR 34.67
He-P 4034.28	10 CFR 34.69
He-P 4034.29	10 CFR 34.71
He-P 4034.30	10 CFR 34.73
He-P 4034.31	10 CFR Part 34, Subpart E (10 CFR 34.75)
He-P 4034.32	10 CFR 34.79
He-P 4034.33	10 CFR 34.81
He-P 4034.34	10 CFR 34.83
He-P 4034.35	10 CFR 34.85
He-P 4034.36	10 CFR 34.87
He-P 4034.37	10 CFR 34.89
He-P 4034.38	10 CFR 34.101
He-P 4034.39	10 CFR 34.41
He-P 4034 Appendix A	10 CFR Part 34, Appendix A

### Appendix C

<u>Rule</u>	<u>Title</u>	<u>How to Obtain and Cost</u>
He-P 4034.06(a)	American National Standard Institute, N-432-1980- “Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography,” <del>published</del> published as NBS Handbook 136, issued January 1981.	American National Standards Institute, Inc. 25 West 43 <sup>rd</sup> Street, New York, New York 10036 (212) 642- 4900, information about obtaining a copy for review is available at: <a href="http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html</a> .